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10/715,482	11/19/2003	Naveen Arora	2761-0169P	3751

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
04/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/715,482	ARORA ET AL.	
	Examiner	Art Unit	
	VANESSA L. FORD	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,21 and 35-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,21 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's request for continued examination filed March 3, 2008 is acknowledged. Applicant's amendment filed July 2,2007 has been entered. Claim 1 has been amended. Claims 2, 9-20 and 22-34 have been canceled. Claims 27-29 have been added. Claims 1, 3-8, 21 and 35-38 are under examination.

Rejection Withdrawn

2. In view of Applicant's amendment the following the rejections are withdrawn:

(a) rejection of claims 1, 3-8, 21 under 35 U.S.C. 112, first paragraph is maintained for the reasons set forth on pages 5-9, paragraph 5 of the Final Office Action.

(b) rejection of claims 1, 3-8 and 21 under 35 U.S.C. 112 second paragraph, page 16, paragraph 10 of the Final Office action.

Rejections Maintained

3. The rejection of claims 1, 3-8, 21 and 35-38 under 35 U.S.C. 112, first paragraph is maintained for the reasons set forth on pages 2-5, paragraph 9 of the Final Office Action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which lacks written description in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention.

The claims are directed to a novel protein capable of inhibiting anthrax toxin activity. Claim 21 recites "the protein of claim 1, wherein the grass is selected from the group consisting of *Imperata cylindrica, Lolium perenne, Phleum pratense* and *Cynodon dactylon*". Therefore, the claims encompass a genus of 67 kDa proteins.

The specification only provides written description for the 67 kDa protein isolated from *Imperata cylindrica.* There is no disclosure that the claimed protein was isolated from a grass other than *Imperata cylindrica.* The instant specification does not describe a 67 kDa protein isolated from *Lolium perenne, Phleum pretense* or *Cynodon datylon.*

Bijli et al (*Clin. Exp. Allergy, January 2003, 33:65-71)* teach a 67kDa protein purified from *Imperata cylindrica* (page 65). Verma et al *(International Archives of Allergy and Immunology, 2000, 122:251-256)* teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 252). Therefore, one of skill in the art would not conclude that the claimed novel 67-kda protein could be isolated from a grass other than *Imperata cylindrica*. One skilled in the art would not conclude that Applicant was not in possession of the claimed 67 kDa proteins isolated from the genus of *Lolium,*

Cynodon and *Phleum* at the time of filing. Therefore, Applicant has not met the written description requirements as set forth in 35 U.S.C. 112, first paragraph.

Applicant's Arguments

Applicant urges that the present specification provides adequate written description as to the isolation of pollen grains from *Imperata cylindrical* and genera of *Lolium, Phleum* and *Cynodon*. Applicant directs the Examiner to pages 2, 8, 9 and the Examples as well as Figure 3 disclosed in the specification to support their position.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed July 2, 2007 have been fully considered but they are not persuasive.

It must be remembered that this rejection is made under 35 U.S.C. 112, first paragraph and is set forth as a written description rejection. It must be also be remembered that 35 U.S.C. 112, first paragraph (written description) requires that Applicants were in possession of the claimed invention at the time of filing. The rejection under 112 first paragraph was set forth because according to the instant disclosure, Applicants were only in possession of a 67 kDa protein that was isolated from *Imperata cylindrical* and not from *Lolium perenne*, *Phleum pretense* and *Cynodon dactylon*. It is established in art that the claimed 67 kDa protein can be isolated from *Imperata cylindrical.* Nowhere in the instant specification have Applicants disclosed a 67 kDa protein isolated from other genus such as *Lolium*, *Phleum* and *Cynodon* as claimed by Applicants. Therefore, the specification also fails to provide adequate written description for claimed protein isolated from *Lolium*

perenne, Phleum pretense or *Cynodon datylon.* Therefore, one skilled in the art would not conclude that Applicants were in possession of 67 kDa proteins isolated from *Lolium perenne, Phleum pretense* or *Cynodon datylon* at the time of filing.

To address Applicant's comments regarding cross-reactivity and Figure 3(a) of the instant specification, figure 3(a) shows cross-reactivity of 67 kDa hypersensitive sera to *Imperata cylindrica, Cynodon datylon, Lolium perenne and Phleum pratense*. This figure does not show evidence that Applicant's were in possession of the claimed invention at the time of filing of a 67-kDa protein isolated from *Cynodon dactylon, Lolium perenne and Phleum pretense.* The figure shows cross-reactivity of 67 kDa hypertensive sera specific to *Imperata cylindrica, Cynodon datylon, Lolium perenne and Phleum pratense.* See page 6 of the instant specification. Figure 3 in no way shows that tropical grasses; *Cynodon dactylon, Lolium perenne and Phleum pratense* have a 67-kDA protein. At most, the specification shows that *Cynodon datylon, Lolium perenne and Phleum pratense* have at least one common epitope.

For the reasons set forth above, this rejection is maintained.

4. The rejection of claims 1, 3-8, 21 and 35-38 under 35 U.S.C. 102(a) as anticipated by Bijli et al *(Clin. Exp. Allergy, January 2003)* is maintained for the reasons set forth on pages 9-11 paragraph 6 of the Final Office Action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection was on the grounds that Bijli et al teach a 67kDa protein purified from *Imperata cylindrica* (page 65). Bijli et al teach a protein that is stable at room temperature (see Abstract). Bijli et al teach a 67kDa protein binds IgE (page 68). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner", "is devoid of any carbohydrate moiety", "wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that Bijli et al, 2003 do not teach the purification of an isolated 67-kDa protein. Applicant urges that the protein of the prior art was only observed on SDS-PAGE and Western blot. Applicant urges that the presentation of side-by-side evidence comparing the claimed protein and the protein of the prior art in the form of a declaration is not necessary.

Applicant urges that claim 37 states that the protein is purified by hydrophobic column chromatography and therefore recites how the protein is isolated. Applicant

urges that Bijli 2003 is not isolated and may be a mixture of proteins with or degradation products of high molecular weight proteins.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed July 2, 2007 have been fully considered but they are not persuasive.

Bijli et al, 2003 teach an isolated 67 kDa protein extract from *Imperata cylindrica* using EACA and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract and Figure 2). Bijli et al, 2003 teach an isolated protein because the protein is analyzed by SDS-PAGE. It is noteworthy to point out that Bijli et al, 2003 makes reference to a 67 kDa protein from *Imperata cylindrical* in the Introduction section on page 65 of Bijli et al.

To address Applicant's comments regarding purification, it should be noted the claims are directed to a product and Applicant is arguing process limitations (e.g. the protein of the prior art was only observed on SDS-PAGE) of the claimed product. Applicant is also arguing process limitations of the claimed protein by directing the Examiner to claim 37. It should be further noted that the claims do not recite how the protein is isolated. It should be remembered that the term "isolate" is defined as separating something from something else. The prior art teaches that the 67-kDa protein has been extracted by EACA and isolated on SDS gel. See page 68. It should be remembered that the product (e.g. 67-kDa protein) of Bijli et al, 2003 is the same as the product claimed by the applicant because they appear to possess the same or

similar functional characteristics. It should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

To address Applicant's comments regarding a side-by-side comparison, Applicant has not submitted any evidence to point to the differences between the claimed protein and the protein of the prior art.. Since the protein of the prior art and the claimed protein are the same they would necessarily possess all of the same biological activities as the claimed protein. Bijli et al, 2003 anticipate the claimed invention.

In view of all of the above, this rejection is maintained.

5. The rejection of claims 1-8, 21 and 35-38 under 35 U.S.C. 102(b) as anticipated by Bijli et al *(Journal of Immunological Methods 260 (Feb. 2002, 91-96)* is maintained for the reasons set forth on pages 11-12, paragraph 7 of the Final Office Action.

The rejection is reiterated below:

The rejection was on the grounds that Bijli et al teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 93, Figures 1 (a)-(c)). Bijli et al teach a protein that is stable at room temperature (page 92). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner" and "is devoid of any carbohydrate moiety", wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" "wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that a protein cannot be isolated without a purification process. Applicant urges that Bijli et al, 2002 fails to teach that a 67-kDa protein is isolated from *Imperata.* Applicant urges that the protein of the prior art was only observed on SDS-PAGE. Applicant urges that the presentation of side-by-side evidence comparing the claimed protein and the protein of the prior art in the form of a declaration is not necessary.

Applicant urges that claim 37 states that the protein is purified by hydrophobic column chromatography and therefore recites how the protein is isolated. Applicant urges that Bijli et al, 2002 is not isolated and may be a mixture of proteins with or degradation products of high molecular weight proteins.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed July 2, 2007 have been fully considered but they are not persuasive.

Bijli et al, 2002 do teach an isolated 67 kDa protein extract from *Imperata cylindrica* and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract, pages 92-93 and Figure 1). Bijil et al teach that the samples were prepared by the method of Kumar et al, 1998 which teaches a pollen extraction method. Therefore, the proteins were extracted from *Imperata cylindrica.* Since the protein of the prior art and the claimed protein are the same they would necessarily possess all of the same biological activities.

To address Applicant's comments regarding purification, it should be noted the claims are directed to a product and Applicant is arguing process limitations (e.g. the protein of the prior art was only observed on SDS-PAGE) of the claimed product. Applicant is also arguing process limitations of the claimed protein by directing the Examiner to claim 37. It should be further noted that the claims do not recite how the protein is isolated. It should be remembered that the term "isolate" is defined as separating something from something else. Thus, the prior art teaches that the 67-kDa

protein has been extracted and isolated on SDS gel. It should be remembered that the product (e.g. 67-kDa protein) of Bijli et al, 2002 l is the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. It should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

To address Applicant's comments regarding a side-by-side comparison, Applicant has not submitted any evidence to point to the differences between the claimed protein and the protein of the prior art. Since the protein of the prior art and the claimed protein are the same they would necessarily possess all of the same biological activities. Bijli et al, 2002 anticipate the claimed invention.

In view of all of the above, this rejection is maintained.

6. The rejection of claims 1, 3-8, 21, 35-36 and 38 under 35 U.S.C. 102(b) as anticipated by Verma et al *(International Archives of Allergy and Immunology, 2000, 122:251-256)* is maintained for the reasons set forth on pages 12-15, paragraph of the Final Office Action.

The rejection was on the grounds that Verma et al teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 252). Verma et al teach a protein that is stable at room temperature (page 252). Verma et al teach the 67-kDa protein is a cross-reactive allergen (see the Abstract). Verma et al teach that the 67-kDa protein has at least three antigenic determinants (see the Abstract). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner" and "is devoid of any carbohydrate moiety", wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that the isolated protein of Verma et al is different from the claimed isolated protein. Applicant states that Verma et al's protein is different from the presently claimed protein because the claimed protein can be sequenced using Edman

degradation where as Verma et al 's protein cannot be sequenced. Verma et al purify their protein to a single band by SDS-PAGE analysis.

Applicant refers to the declaration submitted under 37 CFR. 1.1.32 filed February 6, 2006.

Applicant urges that Verma et al cannot anticipate the claimed invention.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed July 2, 2007 have been fully considered but they are not persuasive.

The declaration of Naveen Arora under 37 CFR 1.132 filed February 6, 2006 is insufficient to overcome the rejection of claims 1, 3-8, 21, 35-36 and 38 based upon Verma et al as set forth in the Final Office action. As previously stated, the Declaration submitted by Naveen Arora merely discusses the differences in extraction and purification of the protein. The declaration concludes that since the protein of the prior art cannot be sequenced then the claimed protein and the protein of the prior art are different. As stated below, the purification or production of a product does not impart novelty or unobviousness. The declaration has failed to provide evidence that the claimed protein and the protein of the prior art are different.

Verma et al teach an isolated 67 kDa protein extract from *Imperata cylindrica* and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract, page 252 and Figure 4). Verma et al also teach that the 67 kDa protein was purified using various chromatography methods (page 252).

To address Applicant's comments regarding the protein bands disclosed on the immunoblots of the prior, it should be noted that among the protein bands disclosed, the prior art teaches a stable 67 kDa protein. See pages 253 and 254, figure 2, Ic-VIII. The claims are directed to an isolated 67-kDa protein and not a purification method for obtaining the isolated 67 kDa protein. The product (e.g. 67-kDa protein) of Verma et al is the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. It should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

To address Applicant's arguments regarding the inability of Verma et al's protein to be sequenced, it should be noted that there are no limitations in the claims that

require that the protein is sequenced. It should be noted that because the protein's N-terminal was blocked does not mean that the protein of the art and the claimed protein are different. Applicant has not shown any structural differences between the claimed 67-kDa protein and the 67Kda protein taught by Verma et al. Since the protein of the prior art and the claimed protein are the same they would necessarily possess all of the same biological activities.

Verma et al anticipate the claimed invention.

7. The rejection of claim 6 under 35 U.S.C.112 second is maintained for the reasons set forth on page 16, paragraph 10 of the Final Office Action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection was on the grounds that claim 6 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites "… wherein the protein in the range of about 15-5 ng partially inhibits the cleavage of 5µg of the protective antigen of Bacillus anthracis by trypsin". It is unclear as to what Applicant is referring. How much cleavage is being inhibited? Clarification is required

Applicant Arguments

Applicant urges that the phrase" partially inhibits" means that cleavage of protective antigen was inhibited in a dose dependent manner and at this concentration it does not inhibit completely". Applicant urges that the word "partially' has been deleted from claim 6.

Examiner's Response to Applicant's Arguments

It is the Examiner's position that the phrase "partially inhibits" is unclear. It should be noted that "partially" has not been deleted from claim 6. Thus, this rejection is maintained.

Status of Claims

8. No claims allowed.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Examiner, Art Unit 1645
March 18, 2008

/N. M. Minnifield/
Primary Examiner, Art Unit 1645